Faculty of Pharmacy

Syllabus For

Master of Pharmacy

(M. Pharm. Programme)

Effective From: JUNE -2011
M. Pharm. Syllabus (Pharmaceutics)
Semester I
Paper Code PY10001
MODERN ANALYTICAL TECHNIQUES
(Common to all branches)
Theory (60 Hours) (Four hours per week, 4 Credits)

1. UV-VISIBLE SPECTROSCOPY:

2. INFRARED SPECTROPHOTOMETRY:
Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:
Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

4. MASS SPECTROMETRY:
Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.
5. ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY: (3)
Principle, instrumentation, interferences and applications in Pharmacy.

6. X-RAY DIFFRACTION METHODS: (3)
Introduction, generation of X-rays, X-ray diffraction, Bragg’s law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

7. OPTICAL ROTARY DISPERSION: (3)
Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

8. THERMAL METHODS OF ANALYSIS: (4)
Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

9. CHROMATOGRAPHIC TECHNIQUES: (15)
a) Classification of chromatographic methods based on mechanism of separation, Theories of chromatographic separation.
b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.
c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS: (3)
Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY: (3)
Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT.
MODERN ANALYTICAL TECHNIQUES (PY10001P)

Practical:

(Six hours per week, 6 Credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
   a. Vitamins
   b. Oral antidiabetics
   c. NSAIDs
   d. Antimicrobials
   e. Antihistamines
   f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
8. Experiments of Chromatography.
   a. Thin Layer Chromatography.
   b. Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
11. Any other relevant exercises based on theory.

Recommended books:

8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
Pharmaceutics  
Semester I  
Paper code-PY10101  
Subject: - Core elective-I  
PHARMACEUTICAL FORMULATION, DEVELOPMENT & BIOPHARMACEUTICS  
(Theory)  
(Four hours per week, 4 Credits) Total: 60 hours

1. Pre-formulation studies  
(a) Physical, Chemical and Pharmaceutical factors influencing formulation  
(b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties  
(c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form  
(d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.  
(e) Drug-excipient compatibility study  
(f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).  
(g) Pre-formulation studies of Biotechnological derived products and reference guidelines.

2. Solubilization and solubilized system  
(a) Theoretical aspects and applications.  
(b) Techniques for improvement in drug solubilization for development of various dosage forms.

3. Dissolution study  
(a) Importance, objectives, equipments,  
(b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development.  
(c) Selection of dissolution media and conditions.
Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.

4. Stability Study

(a) Basic concept and objectives of stability study,
(b) Order of reaction and their applications in predicting shelf life and half life of pharmaceutical formulations,
(c) Importance of accelerated stability study,
(d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.
(e) Regulatory requirements related to stability testing with emphasis on matrixing / bracketting techniques, climates zone, impurities in stability study, photostability testing etc.,
(f) Applications of microcalorimetry in stability study.

5. Drug Absorption

(a) Factors affecting drug absorption; i.e. Physicochemical, Physiological and Pharmaceutical.
(b) Method of studying bioavailability and bioequivalence.
(c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

6. Pharmacokinetic parameters

(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, absorption rate constant, elimination rate constant.
(b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.

7. In-vitro In-vivo Correlation (IVIVC)

(a) Methods of establishing IVIVC
(b) Factors affecting IVIVC

8. Cosmetic, Dental and Herbal products

(a) Formulation and evaluation of various cosmetic and dental products
(b) Formulation and evaluation of products containing herbal ingredients.

Books Recommended:

3. Pharmaceutics “The Science of Dosage form design” by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
7. Pharmaceutical dissolution testing by Banaker.
9. Techniques of Solubilization of Drugs by Yalkowsky.
13. Pharmacokinetics by Welling and Tse.
14. Pharmacokinetics by Gibaldi and Perrier
16. Pharmacokinetics for pharmaceutical scientist by John Wagner.
17. Dissolution, Bioavailability and Bioequivalence by Abdul.
18. Clinical Pharmacokinetics, Concepts and applications by Rowland and Tozer.
21. Perfumes, Cosmetics and Soaps by Poucher.
Semester I
Paper code-PY10101P
Subject: - Core elective-II

PHARMACEUTICAL FORMULATION, DEVELOPMENT & BIOPHARMACEUTICS (PRACTICAL)
(Six hours per week, 6 Credits)

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. To prepare, evaluate pallets by Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.
10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating (Dip Coating)
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.
Semester I
Paper code-PY 10201
Subject: - Core elective -III
INDUSTRIAL PHARMACY (THEORY)
(Four hours per week, 4 Credits Total: 60 hours)

1. Pharmaceutical factory location: Selection, layout and planning. Utility services, Service facilities, HVAC and personnel facilities. 8 hr
2. Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms like solids, liquids, semisolids and sterile. 8 hr
3. Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M. 8 hr
4. Preparation of documents like batch manufacturing record, batch packing record, validation protocols. 8 hr
5. Preparation of standard operative procedure (SOPs) for equipments and manufacturing or processing steps. 6 hr
6. GMP and its implementation 7 hr
7. Production planning and materials control. 7 hr
8. Pilot plant, scale up technique. 8 hr

References:
1. Lachman “The theory and Practice of Industrial Pharmacy
2. Remingtons “Pharmaceutical Sciences”
3. Bentley’s Pharmaceutics.
4. Pilot plants model and scale-up methods, by Johnstone and Thring.
5. GMP practices for pharmaceutical –James Swarbrick.
6. How to practice GMPs by P.P.Swarbrick.
7. Chemical Engineering Plant Design by Vibrant.
Semester – II
Paper Code: PY20001

RESEARCH METHODOLOGY
(Common to all branches)

Theory (60 Hours) (Four hours per week, 4 credits)

1. Research: Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research. (4)

2. Literature survey: Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey. (3)

3. Selecting a problem and preparing Research proposals. (3)

4. Methods and tools use in research :
   a. Qualities studies, quantitative studies
   b. Simple data organization descriptive data analysis,
   c. Limitation & sources of Error
   d. Inquiries in form of Questionnaire, etc. (12)

5. Documentation:
   a. “How” of documentation
   b. Techniques of documentation
   c. Importance of documentation
   d. Use of computer packages in documentation. (11)


Different parts of the Research paper
1. Title –Title of project with authors name
2. Abstract- Statement of the problem, Background list in brief and purpose and scope.
3. Key Words.
5. Results- tables, graphs, figures & statistical presentation.
6. Discussion support or non support of hypothesis, practical & theoretical Implications
7. Conclusion
8. Acknowledgements.
9. References
10. Errata
11. Importance of Spell check for entire project
12. Uses of footnotes

7. **Presentation** (especially for oral presentation): (6)
   Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire.

8. Cost analysis of the project: cost incurred on raw materials, Procedure, instrumentations and clinical trials. (3)

9. Sources for procurement research grants: international agencies, Government and private bodies. (3)

10. Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries. (3)

**References Books:**

1. Research In Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
3. Practical Introduction o copyright.- Gavin Mcfarlane
5. Scientist in legal Systems- Ann labor science
7. Writing a technical paper- Donald Menzel
9. Protection of industrial Property rights- P. Das & Gokul Das
10. Spelling for the millions- Edna Furmess
11. Preparation for publication – King Edward Hospital Fund for London
12. Information Technology – The Hindu speaks
15. Manual for the preparation of industrial feasibility studies
Semester – II  
Paper code-PY20101  
Core elective-IV  
NOVEL DRUG DELIVERY SYSTEM PART-I  
Theory  
(Four hours per week, 4 credits)

1. Recent Innovations in Conventional Dosage Forms – including site specific and time release modulations.  
e.g. : Tablets : Osmotic, Colon target, Gastro-retentive, Buccal, Sublingual.  
Capsules : Modified release,  
Semi-solids :  
Parenterals :  
Powders : Particle coating, Taste-masking,  
Liquids :  

2. Packaging components and its evaluation: factors affecting selection, Types and classification, Primary and secondary and regulatory aspects.  
Contribution in stability of the dosage forms.

Semester – II  
Core elective VI  
Paper code: PY20101P  
NOVEL DRUG DELIVERY SYSTEM-I (PRACTICAL)  
(Six hours per week, 6 credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

References Books: 
3. Pharmaceutics “The Science of Dosage form design” by Aulton
4. Pharmaceutical dispensing by Husa.
5. Modern pharmaceutics by G. S. Banker.
7. Pharmaceutical dissolution testing by Banaker.
Semester – II  
Core elective V  
Paper code: PY20201  
GLOBAL REGULATORY REQUIREMENTS (THEORY)  
(Four hours per week, 4 credits)  

1. Validation of Pharmaceutical Processes, equipments/apparatus, basic  
   concept in analytical method development for dosage forms., Computer System validation, ERP  
   and SAP systems.  

2. Basics in Drug approval process with reference to:  
   Orange book, Freedom of information, IIG, DMF, Historical aspects with Various phases of drug  
   development and approval.  

3. IND, NDA, ANDA, Concept of para I to IV, exclusivity: Content, format and  
   Application.  

4. Brief and comparative introduction to various regulatory agencies:  
   USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.  

References Books:  
The guidance documents shall be procured from the website of the respective Government.
Semester – III
Subject Code PY30001
EXPERIMENTAL DESIGN AND PATENTS
(Common Subject for all branches)
Theory (60 Hours) (Four Hours per week, 4 credit)

1. Experimentals Designs (20)
Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.

2. Patents (25)
Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, Important patent related websites.

3. Brief introduction to trademark protection and WO patents (15)
Introduction to “The Patents Act 1970” and “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent.

Reference Books:
3. Henri J A Charmasson and John Buchaca, Patents, Copyrights & Trademarks For Dummies, 2 nd edition
Semester – III
Core elective VII
Paper code: PY30101
NOVEL DRUG DELIVERY SYSTEM: II
(Four hours per week, 4 credits)

1. Polymer Science Application: Classification, Properties, IIG status and impurity profile, Mechanisms of biodegradation and application in dosage forms. 15 hr

2. Basic Techniques for development of NDDS: Nanotechnology, Bioadhesive systems, Insitu gels, Intelligent drug delivery, tailor made medicines, Strips, Disketts and film products. Liposomes/neosomes. Iontophoretic and sonophoretic systems. 25 hr

3. Use of Spherical Techniques, Super and sub-critical fluids, PEGylations. Biotech Based Products, Proteins and peptides, gene therapy, biomarkers, theranostics, Immunomoduated molecules. Prodrug approach. 20 hr

Semester – III
Core elective- VIII
Paper code: PY30101P
(Six hours per week, 6 credits)
NOVEL DRUG DELIVERY SYSTEM: PART – II

Practical
Development of NDDS using novel polymers and technologies studied in theory (as described above)

Recommended Books:
1. Encyclopedia of pharmaceutical technology; volume 9 Metered dose inhalers


10. Encyclopedia of pharmaceutical technology – volume –16


14. Oral-Lipid Based Formulations: Enhancing the Bioavailability of Poorly Water-soluble Drugs, edited by David J. Hauss


17. Polymeric drug delivery systems, edited by glen s. kwon drug and the pharmaceutical sciences. Vol 148


M. Pharm. Syllabus (Quality Assurance)
Semester I
Paper Code PY10001
MODERN ANALYTICAL TECHNIQUES
(Common to all branches)
Theory (60 Hours) (Four hours per week, 4 Credits)

1. UV-VISIBLE SPECTROSCOPY:

2. INFRARED SPECTROPHOTOMETRY:
   Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:
   Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D-NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

4. MASS SPECTROMETRY:
   Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption/ ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.
5. ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY: (3)  
Principle, instrumentation, interferences and applications in Pharmacy.

6. X-RAY DIFFRACTION METHODS: (3)  
Introduction, generation of X-rays, X-ray diffraction, Bragg’s law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

7. OPTICAL ROTARY DISPERSION: (3)  
Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

8. THERMAL METHODS OF ANALYSIS: (4)  
Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

9. CHROMATOGRAPHIC TECHNIQUES: (15)  
a) Classification of chromatographic methods based on mechanism of separation, Theories of chromatographic separation.  
b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.  
c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS: (3)  
Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY: (3)  
Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT.
12. Reference standards:

Source, preparation, characterization, usage, storage and records.

MODERN ANALYTICAL TECHNIQUES (PY10001P)

Practical:

(Six hours per week, 6 Credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
   a. Vitamins
   b. Oral antidiabetics
   c. NSAIDs
   d. Antimicrobials
   e. Antihistamines
   f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
8. Experiments of Chromatography.
   a. Thin Layer Chromatography.
   b. Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
11. Any other relevant exercises based on theory.

Recommended books:

8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
1. Biological Standardization: (4)

2. Sterility Tests: Methodology & Interpretation. (4)

3. Pyrogen: (5)
   Chemistry and properties of bacterial pyrogens and endotoxins. Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests.

4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. (5)

5. Microbiological Limit Tests, Tests for effectiveness of antimicrobial preservatives. (6)

6. Radio immunoassay: (4)
   General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.

7. Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 & ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity and mutagenicity. (7)

8. Clinical Research: (10)
   b. Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study.
   c. Good Clinical Practices.

9. Bioavailability: (7)
   Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.
Pharmacokinetics: (8)

Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

BIOLOGICAL EVALUATION AND CLINICAL RESEARCH (PY10102P)

Practical

(Six hours per week, 6 Credits)

1. Bio-analytical method development and its validation.
2. Analysis of biological fluids.
3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. Any other relevant exercises based on theory.

Recommended books:

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
10. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
11. Welling and Tse.-Pharmacokinetic
12. Gibaldi and Perrier-Pharmacokinetics
14. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
Semester I

Paper Code PY10202

GOOD MANUFACTURING AND GOOD LABORATORY PRACTICE

Theory (60 Hours)

(Four hours per week, 4 Credits)

1. Concepts of Philosophy of QA, GMP, GLP (3)

2. Good Manufacturing Practices:
   a. Organization & Personnel, responsibilities, training, hygiene. (3)
   b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination. (4)
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP). (4)
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms. (2)
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. (8)
   f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc. (5)
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials. (2)
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities. (6)
   i. Finished product release, quality review, quality audits and batch release documents. (3)
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management. (2)
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing. (2)
1. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents. (2)
2. Waste disposal, scrap disposal procedures and records. (2)
3. Good Laboratory Practices. (4)
4. WHO certification. (2)
5. Testing of Packaging materials. (2)
6. Quality Audit. (2)
7. Specifications for materials, intermediates and finished product. (2)

**Recommended books:**

5. P. P. Sharma “How to practice GLP” Vandana Publication.
7. WHO’s “Drug” Bulletins.
8. Remingtons “Pharmaceutical Sciences”.
9. GMP practices for pharmaceutical-James.
Semester – II
Paper Code PY20001
RESEARCH METHODOLOGY
(Common to all branches)
Theory (60 Hours) (Four hours per week, 4 credits)

1. Research: Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research. (4)

2. Literature survey: Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey. (3)

3. Selecting a problem and preparing Research proposals. (3)

4. Methods and tools use in research :
   a. Qualities studies, quantitative studies
   b. Simple data organization descriptive data analysis,
   c. Limitation & sources of Error
   d. Inquiries in form of Questionnaire, etc.

5. Documentation:
   a. “How” of documentation
   b. Techniques of documentation
   c. Importance of documentation
   d. Use of computer packages in documentation.


   Different parts of the Research paper
   1. Title –Title of project with authors name
   2. Abstract- Statement of the problem, Background list in brief and purpose and scope.
   3. Key Words.
   5. Results- tables, graphs, figures & statistical presentation.
   6. Discussion support or non support of hypothesis, practical & theoretical Implications
   7. Conclusion
   8. Acknowledgements.
   9. References
10. Errata
11. Importance of Spell check for entire project
12. Uses of footnotes

7. **Presentation** (especially for oral presentation): 

Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume—pitch, speed, pause & language, Visual aids & seating, Questionnaire.


9. Sources for procurement research grants: international agencies, Government and private bodies.

10. Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries.

**References Books:**

1. Research In Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
3. Practical Introduction o copyright.- Gavin Mcfarlane
5. Scientist in legal Systems- Ann labor science
7. Writing a technical paper- Donald Menzel
9. Protection of industrial Property rights- P. Das & Gokul Das
10. Spelling for the millions- Edna Furmness
11. Preparation for publication – King Edward Hospital Fund for London
12. Information Technology – The Hindu speaks
15. Manual for the preparation of industrial feasibility studies
Semester – II
Paper Code PY20102
MODERN PHARMACEUTICAL ANALYSIS
Theory (60 Hours)
(Four hours per week, 4 credits)

1. Application of analytical methods to product obtained through genetic engineering, Amino acid sequence analysis, Tryptic mapping, ion exchange amino acid analysis, isoelectric focusing etc. (6)
2. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH. (6)
3. Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action. (6)
4. Applications of various analytical techniques in preformulation analysis and its importance. (6)
5. Analysis of solid oral dosage form. (5)
6. Analysis of injectable dosage form. (5)
7. Compendial testing. (5)
8. Automated analysis. (5)
9. Compendial methods for evaluation of crude drug and herbal formulation. (5)
10. Quality control of radio pharmaceuticals and radio chemical method in analysis. (5)
11. Analysis of cosmetics. (6)

MODERN PHARMACEUTICAL ANALYSIS (PY20102P)
Practical
(Six hours per week, 6 credits)

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
2. Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
3. Determination of Total Chloride in Thiamine Chloride Hydrochloride.
5. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
Determination of related substances in Albendazole, Amiloride, Metronidazole, Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbutazone and Sulphadiazine, Rifampicin as per I.P. Determination of active constituents in crude drugs. E.G. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.

Quality Control tests for some herbal formulations.

Quality Control tests for some cosmetics.

References Books:
2. S. Ahuja, Modern Pharmaceutical Analysis.
4. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia,Vol. I and Vol. II - 1996.The Controller of Publications; New Delhi, Govt. of India,
13. Phytochemical Methods by J.B.Haroborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
Semester – II
Paper Code PY20202
REGULATORY AFFAIRS AND NEW DRUG APPLICATION
Theory (60 Hours)
(Four hours per week, 4 credits)

A. REGULATORY AFFAIRS

1. Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948. (4)
2. Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics - The Drugs & Cosmetic Act 1940 & rules 1945 with amendments. (4)
3. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product. (4)
4. Quality safety and legislation for cosmetic and herbal products. (4)
5. Aims, objects and salient features of following legislations governing Pharmaceutical Industry: Pollution Control Act (6)
   Prevention of Food Adulteration Act 1954
   Industrial Development & Regulation Act 1951
   Consumer Protection Act
7. Drug Master File (Case Study-3 examples). (4)
8. Material Safety Data Sheet (MSDS) preparation. (3)
9. Industrial Safety & Health. (3)
10. Guide lines for filing in countries like US & EU. (5)
11. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US, EU, Japan, ICH. (4)

B. Approval of New drugs:

Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.
References Books:
1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9
3. Deshpande S.W., Drugs and Cosmetic Act 1940.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik
10. The International Pharmacopoeia Vol 1,2,3,4,5 3rd Edition
11. Pollution Control Act, 1974
13. Industrial Development & Regulation Act 1951
17. A.C. Cartwright and Brian Mathews, “International Pharmaceutical Registration” Taylor and Francis Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication
Semester – III
Subject Code PY30001
EXPERIMENTAL DESIGN AND PATENTS
(Common Subject for all branches)
Theory (60 Hours) (Four Hours per week, 4 credit)

1. **Experimentals Designs** (20)
   Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.

2. **Patents** (25)
   Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, Important patent related websites.

3. **Brief introduction to trademark protection and WO patents** (15)
   Introduction to “The Patents Act 1970” and “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent.

**Reference Books:**

3. Henri J A Charmasson and John Buchaca, Patents, Copyrights & Trademarks For Dummies, 2 nd edition
1. **Introduction to Pharmaceutical Validation** (6)
   Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.

2. **Calibration Master plan** (3)

3. **Validation of Equipment** (10)
   Concept of URS, DQ, IQ, OQ & PQ,
   Validation of following equipment
   - Dry Powder Mixers
   - Fluid Bed and Tray dryers.
   - Tablet Compression (Machine)
   - Dry Heat Sterilization/Tunnels
   - Autoclaves
   - Membrane filtration
   - Capsule filling machines.
   - Validation of Integrated lines by media fill test.
   - Validation of existing equipment.

4. **Vendor Certification** (3)

5. **Utilities Validation** (5)
   a. Validation of Pharmaceutical Water System & pure steam,
   b. Validation of HVAC system
   c. Validation of Compressed air

6. **Cleaning Validation: Cleaning of Equipment, Cleaning of Facilities** (3)
7. **Analytical Method Validation**: General principles of analytical method validation. (9)

Validation of following analytical Instruments

- HPLC
- Dissolution test apparatus
- U.V./Visible spectrophotometers

8. **Process Validation** (9)

Prospective, concurrent, retrospective & revalidation, Process validation of following formulations

- Coated tablets
- Capsules
- Ointment/Creams
- Liquid Orals

9. **Computer System Validation** (4)

10. **Product development** (8)

a. In-process controls in manufacturing process design and development of:
- Tablets, Capsules, Liquid orals, Ophthalmic applications, Aerosols and Sterile parenteral
b. Scale up operations, SUPAC guide line.

**VALIDATION AND PRODUCT DEVELOPMENT (PY30102P)**

**Practical**

1. Validation of following equipment
   a. Autoclave
   b. Hot air oven
   c. Powder Mixer (Dry)
   d. Tablet Compression Machine
2. Pre-formulation studies of a model Drug.
3. Validation of analytical method (minimum four exercises).
4. Validation of a processing area.
5. Validation of at least two analytical instruments.
6. Cleaning validation of one equipment.
Recommended Books:


3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.


Semester – III

Paper Code PY30202

INTRODUCTION TO DISSERTATION (For all branches)

Instructions:

1. Student must complete literature search and preliminary experimental work of his/her research project and submit the synopsis, dully signed by Research Guide and Principal of Institute to University on completion of Semester – III.

2. Utmost care should be taken in selection of research topic so that repetition of research work is avoided.

3. For change in research topic, written permission of institute level research committee should be taken.

4. Candidates work will be evaluated by the ex
M. Pharm. Syllabus (Pharmaceutical Management and Regulatory Affairs)

Semester I

Paper Code PY10001

MODERN ANALYTICAL TECHNIQUES

(Common to all branches)

Theory (60 Hours)

(Four hours per week, 4 Credits)

1. UV-VISIBLE SPECTROSCOPY :


2. INFRARED SPECTROPHOTOMETRY :

   Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR) -theory and applications.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY :

   Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

4. MASS SPECTROMETRY:

   Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS),
Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

5. ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY: (3) Principle, instrumentation, interferences and applications in Pharmacy.

6. X-RAY DIFFRACTION METHODS: (3) Introduction, generation of X-rays, X-ray diffraction, Bragg’s law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

7. OPTICAL ROTARY DISPERSION: (3) Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

8. THERMAL METHODS OF ANALYSIS: (4) Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

9. CHROMATOGRAPHIC TECHNIQUES: (15) a) Classification of chromatographic methods based on mechanism of separation, Theories of chromatographic separation. b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC. c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS: (3) Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY: (3)
Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT.

12. Reference standards:
Source, preparation, characterization, usage, storage and records.

MODERN ANALYTICAL TECHNIQUES (PY10001P)

Practical:
(Six hours per week, 6 Credits)
1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
   a. Vitamins
   b. Oral antidiabetics
   c. NSAIDs
   d. Antimicrobials
   e. Antihistamines
   f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
8. Experiments of Chromatography.
   a. Thin Layer Chromatography.
   b. Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
11. Any other relevant exercises based on theory.
**Recommended books:**

8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
1. Concepts of Philosophy of QA, GMP, GLP (3)

2. Good Manufacturing Practices:
   a. Organization & Personnel, responsibilities, training, hygiene. (3)
   b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination. (4)
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP). (4)
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms. (2)
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. (8)
   f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc. (5)
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials. (2)
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities. (6)
   i. Finished product release, quality review, quality audits and batch release documents. (3)
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management. (2)
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing. (2)
1. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents. (2)

m. Waste disposal, scrap disposal procedures and records. (2)

3. Good Laboratory Practices. (4)

4. WHO certification. (2)

5. Testing of Packaging materials. (2)

6. Quality Audit. (2)

7. Specifications for materials, intermediates and finished product. (2)

**Recommended books:**


5. P. P. Sharma “How to practice GLP” Vandana Publication.


7. WHO’s “Drug” Bulletins.

8. Remingtons “Pharmaceutical Sciences”.

9. GMP practices for pharmaceutical-James.

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**Semester I**

**Paper code-PY10103P**

**Subject: - CGMP AND DOCUMENTATION (PRACTICAL)**

**Core elective-II**

(6 hours per week, 6 Credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.
M. Pharm. Syllabus

Semester I

Paper code-PY10203

Subject: - PHARM MANAGEMENT-I (Theory)

(Four hours per week, 4 Credits) Total: 60 hours


2. Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development. (10)

3. Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc. (10)

4. Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management. (12)

5. Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge. (6)

6. Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc. (6)

7. Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. (6)

8. Stress management. (2)
Reference Books:

5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi.
10. Management “Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill”.
Semester – II  
Paper Code PY20001  
RESEARCH METHODOLOGY  
(Common to all branches)  
Theory (60 Hours) (Four hours per week, 4 credits)

1. Research: Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research. (4)
2. Literature survey: Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey. (3)
3. Selecting a problem and preparing Research proposals. (3)
4. Methods and tools use in research: (12)
   a. Qualities studies, quantitative studies
   b. Simple data organization descriptive data analysis,
   c. Limitation & sources of Error
   d. Inquiries in form of Questionnaire, etc.
5. Documentation: (11)
   a. “How” of documentation
   b. Techniques of documentation
   c. Importance of documentation
   d. Use of computer packages in documentation.
   Different parts of the Research paper
   1. Title –Title of project with authors name
   2. Abstract- Statement of the problem, Background list in brief and purpose and scope.
   3. Key Words.
   5. Results- tables, graphs, figures & statistical presentation.
   6. Discussion support or non support of hypothesis, practical & theoretical Implications
   7. Conclusion
   8. Acknowledgements.
   9. References
10. Errata
11. Importance of Spell check for entire project
12. Uses of footnotes

7. **Presentation** (especially for oral presentation): (6)
   Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire.

8. Cost analysis of the project: cost incurred on raw materials, Procedure, instrumentations and clinical trials. (3)

9. Sources for procurement research grants: international agencies, Government and private bodies. (3)

10. Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries. (3)

**References Books:**

1. Research In Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
2. Practical Introduction o copyright.- Gavin Mcfarlane
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furmness
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
14. Manual for the preparation of industrial feasibility studies
Semester II

Paper code-PY20103

Subject: - PHARM MANAGEMENT-II (Theory)

(Four hours per week, 4 Credits) Total: 60 hours

1. Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. (6)

2. Development of efficient work methods, quality control and management of R&D. (3)

3. Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM. (8)

4. Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections. (6)

5. Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms. (4)

6. Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management. (4)

7. Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing mix Role of 7 P’s (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing (8)

9. Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution. (6)

10. Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area. (4)

11. Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting. (6)

Reference Books:
8. Principle and Practice of Marketing in India by Memoria C. B.
11. Production and Operations Management by S.N.Chary
Semester II
Paper code-PY20203
Subject: - Regulatory Affairs-I (Theory)
(Four hours per week, 4 Credits) Total: 60 hours

1. Origin, development, scope, objectives and nature of Pharmaceutical legislation in India. History and ethics of profession of Pharmacy. (4)

2. A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments) (5)

3. The Narcotics Drugs and Psychotropic Substances Act. (5)


5. The Pharmacy Act, 1948. (5)

6. The Drugs and Cosmetics Act, 1940 and Rules there under. (5)

7. Drugs (Price Control) Order in force. (4)

8. Introduction to Intellectual Property Rights; Copy Right Act, Trade Mark Act, Patent Act and Biodiversity Act, WTO, TRIPS and TRIMS. (5)


11. Schedule U requirements- Product development stage documentation, factory procedures – Standard operating procedures and standard test procedures (5)


Reference Books:
1. Original laws published by Govt. of India.
3. Laws of Drugs in India by Hussain.

 Semester II
 Paper code-PY20203P
 Subject: - REGULATORY AFFAIRS-I (Practical)
 Core elective-VI
 (Six hours per week, 6 Credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.
1. **Experimental Designs**

Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.

2. **Patents**

Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, Important patent related websites.

3. **Brief introduction to trademark protection and WO patents**

Introduction to “The Patents Act 1970” and “The Patents Rule 2003”, with special emphasis on the forms to be submitted along with a patent.

**Reference Books:**

3. Henri J A Charmasson and John Buchaca, Patents, Copyrights & Trademarks For Dummies, 2nd edition
1. A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. (6)

2. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis. (3)

3. Loan license (contract manufacture). (3)

4. Recent amendments to Drugs and Cosmetic Act and other relevant rules. (3)

5. Certification and licensing procedures. (4)

6. Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls. (6)

7. Quality, safety and legislation for cosmetic products and herbal products. (5)

8. Approval of New Drug: Investigational new drug (IND) submission, for mat and content of IND, content of investigator brochure, clinical research protocols, objective and protocol design. FDA guidelines for clinical trials, reviews and approval of a clinical study, general consideration of the new drug approval (NDA), specific requirements, content and format of NDA, manufacturing and control requirements of NDA. New Chemical Entity (NCE). (10)

9. International business and inland & foreign trade, procedure of exporting and importing goods. General international environment; political, legal, socio-cultural and economic factors, tax aspects, marketing factors, labour factors and economic integration. BOP analysis, foreign exchange control, governmental policies, international finance, economic community, IMF, managing multinationals/ globalization of operations. (10)

10. Emerging Trends in Biotechnology Patenting. (4)

11. Patent Cooperation Treaty (3)

Reference Books:
2. Original Laws published by Govt. of India.
4. Export Marketing by Cherian and Parab; Himalaya Publishing House, Delhi
5. Handbook of Procedures, Import and Export Promotion; Government of India, New Delhi

Semester III
Paper code-PY30103P
Subject: - REGULATORY AFFAIRS-II (Practical)
(Six hours per week, 6 Credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

Semester – III
Paper Code PY30203
INTRODUCTION TO DISSERTATION (For all branches)

Instructions:
1. Student must complete literature search and preliminary experimental work of his/her research project and submit the synopsis, dully signed by Research Guide and Principal of Institute to University on completion of Semester – III.
2. Utmost care should be taken in selection of research topic so that repetition of research work is avoided.
3. For change in research topic, written permission of institute level research committee should be taken.
4. Candidates work will be evaluated by the external exam.